

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9154

Bartle, J.

October 9, 2013

Elizabeth L. Perugini ("Ms. Perugini" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Edward N. Perugini, Ms. Perugini's spouse, also has submitted a derivative claim for benefits.

her claim was not based, in whole or in part, on any intentional material misrepresentations of fact.<sup>3</sup>

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In May, 2003, Ms. Perugini submitted a completed Green Form to the Trust signed by her attesting physician, Rashmikan Desai, M.D. Based on an echocardiogram dated June 23, 2002, Dr. Desai attested in Part II of claimant's Green Form that Ms. Perugini suffered from moderate mitral regurgitation and an

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$522,266.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. Desai observed that Ms. Perugini had a "[m]itral valve regurgitant jet area to left atrial area [of] 28 percent consistent with moderate mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Desai also measured Ms. Perugini's left atrial antero-posterior dimension as 4.3 cm and her left atrial supero-inferior dimension as 6.03 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b)ii).

In October, 2003, the Trust forwarded the claim for review by Eduardo A. Arazoza, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Arazoza determined that there was a

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4. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary for a Level II claim.

reasonable medical basis for Dr. Desai's findings that Ms. Perugini had moderate mitral regurgitation and an abnormal left atrial dimension.

Based on Dr. Arazoza's findings, the Trust issued a post-audit determination awarding Ms. Perugini Matrix Benefits. Before the Trust paid Ms. Perugini's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Perugini's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Ms. Perugini's claim, on November 22, 2006, this court approved Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out

of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Claimant elected to opt-out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Ms. Perugini's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of Ms. Perugini's claim. As stated in his March 8, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

In Ms. Perugini's study, the use of excessive depth[,] a decreased Nyquist setting, increased gain, the selection and planimetry of backflow, and the overmeasurement of the mitral "jet," as well as the overmeasurement of the left atrial dimension are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation, jet duration or a complicating factor. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. Perugini has only trivial mitral regurgitation--not moderate mitral regurgitation as claimed by the Attesting Physician. There is no reasonable medical basis for a finding of moderate mitral regurgitation based on this study.<sup>5</sup>

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5. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5%

Thus, notwithstanding Dr. Desai's findings at audit, the Trust rescinded its prior post-audit determination letter and issued a new post-audit determination denying Ms. Perugini's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. Perugini contested this adverse determination.<sup>6</sup> In contest, Ms. Perugini argued that the Trust failed to provide substantial evidence of intentional material misrepresentations of fact in connection with her claim, and that, even if the Trust provided such evidence, it was insufficient to outweigh the contrary evidence that no intentional material misrepresentation occurred. In support of this position, Ms. Perugini contended that deference should be shown to the opinions of the attesting physician and the auditing cardiologist, both of whom determined that there was a reasonable medical basis for the claim. Ms. Perugini also noted that she had submitted a second study conducted on a "more sophisticated machine" than the echocardiogram on which the claim is based due to concerns regarding the "low quality condition" of the machine

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5. (...continued)  
RJA/LAA."

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Perugini's claim.

used to conduct the earlier echocardiogram. She comments that the second echocardiogram "suggest[ed] that the claimant did not have a matrix level condition." While she may have a "weak claim," she maintains the open disclosure of this conflicting medical opinion undermines any contention that she intended to mislead the Trust regarding the potential merits of her claim.

The Trust then issued a final post-audit determination, again denying Ms. Perugini's claim. The Trust argued that Ms. Perugini misinterpreted the legal obligations under Audit Rules and that "[t]he burden of proof remains on the Claimant throughout these proceedings" to establish that there is a reasonable medical basis in support of her claim - not on the Trust to prove that intentional material misrepresentations of fact exist. The Trust also asserted that claimant's contest did not satisfy this burden. First, Ms. Perugini conceded that the echocardiogram on which the claim was based was "poorly performed" and that the second, higher quality echocardiogram reflected that Ms. Perugini did not suffer from conditions qualifying her for Level II benefits. Second, the auditing cardiologist's inability to detect all of the misrepresentations in connection with Ms. Perugini's echocardiogram did not satisfy claimant's burden. Dr. Arazoza was neither trained to detect the types of "manipulations employed by [Coastal Cardiac Imaging]" nor familiar with its patterns of activity as described in Dr. Kisslo's report. Third, while claimant raised numerous contentions and criticisms pertaining to Dr. Kisslo's

declaration, she did not identify any alleged errors in Dr. Kisslo's findings.

Claimant disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Perugini's claim should be paid. On August 2, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7348 (Aug. 2, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 24, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and prepare a

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.



report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for her claim. Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Perugini incorporates the arguments she made at contest.<sup>8</sup> In addition, the claimant

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8. Claimant also made repeated reference to a September 8, 2005 letter from Class Counsel to the Trust. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a  
(continued...)

asserts that Dr. Kisslo's report should be stricken as violative of PTO No. 3883 to the extent it constitutes a re-audit of her claim.<sup>9</sup> In response, the Trust argues that it did not re-audit Ms. Perugini's claim. According to the Trust, Dr. Kisslo was hired to assist the Trust in determining whether claims contained intentional material misrepresentations of fact.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Perugini's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

The usual echocardiographic views were obtained. However, the study was not conducted in a manner consistent with medical standards. There was excessive color gain

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8. (...continued)  
fraudulent echocardiogram. Class counsel further maintained that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

9. Claimant also identifies a number of alleged procedural errors by the Trust in connection with her claim: (1) the Trust had a legal obligation to pay Ms. Perugini's claim prior to the May 10, 2004 stay; (2) the Trust should be precluded from contesting Ms. Perugini's claim because it failed to comply with the terms of PTO Nos. 3883 and 5625; and (3) the Trust should be precluded from contesting Ms. Perugini's claim because the Trust failed timely to prosecute her claim. We reject Ms. Perugini's argument that her claim should be paid because the Trust did not comply with the procedural guidelines set forth in our various PTOs. None of the errors Ms. Perugini alleges, even if true, would change our disposition of her claim.

with color artifact seen within the myocardium and outside of the heart. This was particularly evident in the apical views. There was obvious stuttering of images related to persistence causing color artifact. Although the Nyquist limit was appropriately set at 61 cm per second at a depth of 17 cm in the parasternal long-axis view, the Nyquist limit was borderline low at 51 cm per second at a depth of 19 cm in the apical views. In addition, three supposed RJA determinations were performed by the sonographer. These determinations clearly were inaccurate, occurring only in still-frame images and were not representative of the cardiac cycle. In addition low velocity and non-mitral regurgitant flow was included in these determinations.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Perugini had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part:

Visually, only trace mitral regurgitation was apparent on the parasternal long-axis and apical views. I digitized those cardiac cycles in the apical views in which mitral regurgitation could be identified. In spite of increased color gain and persistence, I was able to planimeter the RJA in the mid portion of systole. The RJA was largest in the apical four chamber view and was only within 1 cm of the mitral annulus in the apical two chamber view. The largest representative RJA in the apical four chamber view was 1.0 cm<sup>2</sup>. I determined that the LAA measured 22.0 cm<sup>2</sup> in the apical four chamber view. Therefore, the largest representative RJA/LAA ratio was less than 5%. This study was diagnostic of trace to mild mitral regurgitation. The sonographer-determined RJAs were 2.27 cm<sup>2</sup> and 4.59 cm<sup>2</sup> in the apical four chamber view. The sonographer-determined RJA in the apical two chamber view was 5.82 cm<sup>2</sup>. However, these were still

frame measurements of non-mitral regurgitant flow. The sonographer-determined LAA was 25.14 cm<sup>2</sup>. This was an inaccurate measurement, which included pulmonary veins.

After reviewing the entire Show Cause Record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. Perugini had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante each found that Ms. Perugini's sonographer improperly selected, traced, and measured a supposed regurgitant "jet." According to Dr. Vigilante, the supposed RJAs measured by the sonographer were "still-frame images and were not representative of the cardiac

cycle." In addition, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included artifact resulting from excessive color gain and a low Nyquist to exaggerate the appearance of mitral regurgitation.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Perugini's echocardiogram demonstrated, at most, mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Ms. Perugini had moderate mitral regurgitation. Specifically, he explained that "the largest representative RJA/LAA ratio was less than 5%."

Claimant does not substantively challenge the specific findings of Dr. Kisslo or Dr. Vigilante regarding the manner in which Ms. Perugini's echocardiogram was conducted.<sup>10</sup> In fact, the only substantive evidence upon which claimant relies, a second study performed on a "more sophisticated" echocardiogram machine, undermines the echocardiogram of attestation and supports the conclusions of Dr. Kisslo and Dr. Vigilante that Ms. Perugini did not have moderate mitral regurgitation.

We also reject Ms. Perugini's argument that the review of her claim by Dr. Kisslo constitutes an impermissible second

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10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

audit. This argument ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection with a claim. Specifically, the Audit Rules state, in pertinent part, that:

The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied Ms. Perugini's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

Claimant disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Perugini's claim given our conclusion, based on our review of the entire record, that there is no reasonable

medical basis for Dr. Desai's representation that Ms. Perugini had moderate mitral regurgitation.<sup>11</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that Ms. Perugini had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Perugini's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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11. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.